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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

TORRES-CARDONA et al

Atty. Ref.: **4662-71**

Serial No. **10/685,194**

Group: **1625**

Filed: **October 14, 2003**

Examiner: **OH, Taylor V.**

For: **METHOD FOR PRODUCING ESTERIFIED ASTAXANTHIN FROM ESTERIFIED ZEAXANTHIN**

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September 8, 2006

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICANTS' BRIEF ON APPEAL

Sir:

This Appeal is from the Examiner's twice rejecting claims 1-22, all of the claims presently pending herein.[1] As will become evident from the following discussion, the Examiner's rejections are in error and, as such, reversal of the same is solicited.

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[1] The claims on appeal appear in the Claims Appendix accompanying this Brief.

I. Real Party In Interest

The real party in interest is the owner of the subject application, namely DSM IP Assets B.V.

II. Related Appeals and Interferences

No appeals and/or interferences related to this application are pending.

III. Status of Claims

A. The following claims are presently pending in this application and have been twice rejected in the Examiner's Official Action of May 16, 2006: Claims 1-22.

B. The following claims have been cancelled during prosecution to date: None.

C. The following claims have been allowed: None

IV. Status of Amendments

An Amendment has been filed on September 7, 2006 in advance of the present Brief so as to address (1) antecedent bases issues with respect to certain pending claims and (2) an objection with respect to the specification regarding the Examiner's allegation that Example 3 was missing therefrom. Issue (1) was addressed by suitable minor amendment to the affected claims so as to obviate the antecedent basis rejection raised by the Examiner. Issue (2) was addressed by pointing out to the Examiner that, although the header for Example 3 was orphaned from its following text, the header for Example 3 is in fact present in the last line of paragraph [0029] on page 6 of the originally filed application with the following text of Example 3 being present in paragraphs [0030]-[0034].

Following entry of the Amendment, the only issue to be resolved on appeal therefore is the alleged omission of "essential subject matter" from the claims which gave rise to the Examiner's rejection thereof under 35 USC §112, second paragraph.

V. Summary of Claimed Subject Matter

The present invention as defined by pending independent claim 1 is directed toward a method of preparing esterified astaxanthin from zeaxanthin comprising the steps of acylating zeaxanthin in an organic solvent with an acylating agent to produce esterified zeaxanthin, and contacting the esterified zeaxanthin with an oxidizing agent to produce esterified astaxanthin. (Paragraph [0012])

VI. Grounds of Rejection to be Reviewed on Appeal

1. Claims 1-22 have been twice rejected under 35 USC §112, second paragraph, as allegedly omitting essential steps.

VII. Arguments

1. Claims 1-22 comply fully with the requirements of 35 USC §112.

The only issue raised by the Examiner is with respect to 35 USC §112, second paragraph. Specifically, the Examiner asserts that the temperature and pH of the esterification step is essential and therefore suggests that claim 1 be amended so as to recite that the esterified zeaxanthin is contacted with an oxidizing agent at temperature between 0 to 25^0C and a pH between 1 to 4 to produce esterified astaxanthin. The Examiner's rationale for requiring the particular preferred temperature and pH conditions embraced by the present invention is that the reaction process at a high temperature and a high PH may increase unwanted by-products and that therefore such parameters are essential to the claimed invention.

However applicants note that the present application is silent on the goal "to reduce unwanted by-products" which the Examiner has asserted to be "essential". Hence, this interpretation of the applicants' invention is one the Examiner has formulated on his own and, while perhaps a desirable goal commercially, is not an essential goal of the presently claimed invention. Furthermore, the problem of reducing unwanted by-products is not a problem which must be solved by the present invention. Instead, the problem addressed by the present invention is the production of esterified Astaxanthin from esterified Zeaxanthin. In this context, the applicants' claims define all the essential steps.

With respect to the description of the present invention, the limitations of temperature and pH are described as "preferred embodiments". Thus, in paragraph [0011], the applicants' note that "an embodiment" of the invention is being described. Again in paragraph [0015] is noted that *preferably* the pH of the aqueous oxidizing agent is between 1 to 4, and that the temperature is *preferably* between 0 to 25^0C. In paragraph [0025] the applicants again note that *preferably* the reaction is carried out at a temperature between 0 to 25^0C (more preferably between 0 to 10^0C).

According to MPEP ¶2172.01 "essential matter" to an invention must be defined in an applicants' claim. In this particular instance, however, the preferred limitations of temperature and pH which the Examiner seeks to introduce into the claims are ***not*** "essential", but are merely preferred. The essential aspect of the present invention is a method to produce esterified astaxanthin from esterified zeaxanthin. The ranges of temperature and pH described in the specification are preferred embodiments – no more, no less.

In this regard, applicants note that in Examples 1, 2 and 5 of the subject application no acid (e.g., hydrobromic acid) was used to adjust the pH of the oxidation step in the range of 1-4. Moreover, the estimated pH of such examples according to the applicants would be between 5 to 7 which is greater than the disclosed "preferred" range but which nonetheless produces esterified astaxanthin – i.e., acylating zeaxanthin in an organic solvent with an acylating agent to produce esterified zeaxanthin, and contacting the esterified zeaxanthin with an oxidizing agent to produce esterified astaxanthin. Thus, issues of temperature and pH are aspects of the claimed invention that may be selected by the skilled artisan but are not "essential" to the production of esterified astaxanthin.

Moreover, applicants note that reaction with the oxidizing agent at temperature of less than 0^0C is also possible and that, in order to prevent undesired hydrolysis a pH of greater than 4 may suitably be employed.

Therefore, the process parameters of a temperature range between 0 to 25^0C and a pH range between 1 to 4, while preferred, are not "essential". That is, applicants suggest that an increase in unwanted by-products could possibly be tolerated without departing from the real spirit of the present invention.

The issue presented therefore is not one of "indefiniteness" under 35 USC §112, but instead is one of scope of coverage to be afforded to the invention. To be sure, applicants submit that the claims are entirely definite within the meaning of the statute and to amend the claims in the manner suggested by the Examiner would be unduly restrictive to the scope of protection to which applicants are deemed entitled.

2. Conclusion.

For the reasons advanced, the Examiner's rejection of claims 1-22 under 35 USC §112, second paragraph, on the basis of alleged omission of essential elements is in error and must be reversed. Such favorable action is solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: __________________________
Bryan H. Davidson
Reg. No. 30,251

BHD:fmh

1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

VIII. CLAIMS APPENDIX

1. (Original) A method of preparing esterified astaxanthin from zeaxanthin comprising the steps of:

> acylating zeaxanthin in an organic solvent with an acylating agent to produce esterified zeaxanthin; and
>
> contacting the esterified zeaxanthin with an oxidizing agent to produce esterified astaxanthin.

2. (Original) The method of claim 1, wherein the organic solvent is selected from the group consisting of chloroform and methylene chloride.

3. (Original) The method of claim 1, wherein the acylating agent is selected from the group consisting of RCOOH, RCOCl and $(RCO)_2O$, wherein R is a hydrocarbon chain of 2-20 hydrocarbons.

4. (Original) The method of claim 3, wherein R is a hydrocarbon chain of 2-8 hydrocarbons.

5. (Original) The method of claim 3, wherein R is a hydrocarbon chain of 2-4 hydrocarbons.

6. (Original) The method of claim 3, wherein the acylating agent is acetic anhydride.

7. (Original) The method of claim 1, wherein the oxidizing agent is prodeuced by mixing a saturated aqueous solution selected from the group consisting of sodium sulfite, potassium sulfite, sodium hydrogen sulfite, potassium hydrogen sulfite, sodium bisulfite and potassium bisulfite, with a saturated solution of a bromate salt.

8. (Original) The method of claim 7, wherein the oxidizing agent is produced by mixing a saturated aqueous solution of sodium bisulfite with a saturated solution of sodium bromate.

9. (Original) The method of claim 8, wherein the ratio of sodium bisulfite to sodium bromate is 1.5:1.

10. (Original) The method of claim 7, wherein the oxidizing agent is produced by mixing a saturated aqueous solution of sodium bisulfite with a saturated solution of potassium bromate.

11. (Original) The method of claim 7, wherein the oxidizing agent is produced by mixing a saturated aqueous solution of sodium bisulfite with a saturated solution of calcium bromate.

12. (Original) The method of claim 7, wherein the oxidizing agent is produced by mixing a saturated aqueous solution of sodium bisulfite with a saturated solution of cerium bromate.

13. (Previously Presented) The method of claim 1, which is practiced at a reaction temperature between 0 to 25^0C.

14. (Previously Presented) The method of claim 7, wherein the oxidizing agent and the zeaxanthin esters are present in a ratio of the oxidizing agent to the zeaxanthin esters of between 0.5 to 5 parts for each part of carotenoid.

15. (Previously Presented) The method of claim 7, wherein the aqueous oxidizing agent has a pH of between 1 to 4.

16. (Previously Presented) The method of claim 2, wherein the organic solvent and zeaxanthin esters are present in a ratio of the organic solvent to the zeaxanthin esters of between 5 to 40 parts for each one.

17. (Original) The method of claim 1, wherein the zeaxanthin is obtained by saponification of a plant extract.

18. (Original) The method of claim 17, wherein the plant is marigold.

19. (Original) The method of claim 1, wherein the zeaxanthin is prepared synthetically.

20. (Original) The method of claim 1, further comprising the step of washing the esterified zeaxanthin with water before contacting the esterified zeaxanthin with the oxidizing agent.

21. (Original) An astaxanthin diester produced by the method of claim 1.

22. (Original) The astaxanthin diester of claim 21 which is an astaxanthin diacetate.

IX. EVIDENCE APPENDIX

[NONE]

X. RELATED PROCEEDINGS APPENDIX

[NONE]

XI. CERTIFICATE OF SERVICE

[NOT APPLICABLE]